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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,411	10/17/2005	Michael Brian Edward Bremner	1171/42784/157-PCT-US	9055

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EXAMINER	
OSTRUP, CLINTON T	
ART UNIT	PAPER NUMBER
3771	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,411	BREMNER ET AL.	
	Examiner	Art Unit	
	CLINTON OSTRUP	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-8,10-17 and 26-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6-8,10-17 and 26-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 May 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 3-4, 6, 8, 10-17, and 26-36 are pending in this application. Claims 2, 5, 7, 9, and 18-25 have been cancelled.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

A non-initialed and/or non-dated alteration changing April 27, 2005 to April 29, 2005 appears 9 lines down on the first page of the Declaration.

Specification

3. The disclosure is objected to because of the following informalities: Applicant's amendment to the specification is objected to because replacement paragraphs must include markings to show the changes. See: MPEP 714 (II)(B) - Amendments to the Specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1, 3-4, 6, 8, 11, 13, & 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Murray, (EP 0567158A2).**

Regarding claim 1, Murray discloses a system for delivering a supply of gases (6) to a patient comprising a gases supply (4) providing a flow of gases (37) a humidifier (Figure 1) receiving said gases from said gases supply (4) and capable of humidifying said flow of gases up to a level of humidity prior to delivery to said patient, a conduit (66) conveying said flow of gases from said humidifier to said patient, a sensor (34) to sense the temperature of said flow of gases, said sensor in use being releasably coupled in line between said humidifier (34) and said conduit (66) and a filter material (18) such that the sensor is exposed to said flow of gases through said filter material (Figure 5).

Regarding claim 3, the system disclosed by Murray has a sensing means (34) contained in a cartridge (26) such that said sensor (34) is exposed to said gases flow and Murray also discloses a system with an open tubular section (Figures 6 & 7).

Regarding claim 4, Murray discloses a sensor (34) contained in a housing (26) and said housing extending through or residing within an open tubular section and the housing being exposes to said flow of gases. See: Figure 2.

Regarding claim 6, Murray discloses a port (24) and the housing (26) fits into the port to seal the system (Figure 10).

Regarding claim 8, Murray discloses a system with a housing exposed to a flow of gases that is covered by a filter material (18). See: figures 6-7.

Regarding claims 11 &13, Murray's microporous wall (18) is a semi permeable material (i.e. it is microporous). See: col. 2, lines 34-45.

Regarding claim 15-17 the system taught by Murray includes a temperature sensor (34) that is connected to a heater (22). See: figure 2. Murray teaches that the heating element is located in a humidification chamber and it heats water and gasses passing through the humidification chamber to produce humidified gasses to be provided to the patient. Murray discloses a system where connections are formed between one side of said cartridge and the other side of said cartridge or open tubular section and said transportation means (Figure 3). See: col. 1, line 25 - col. 2, line 10; and Figures 1-13.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 3-4, 6, 8, 10-17, and 26-36 rejected under 35 U.S.C. 103(a) as being unpatentable over Gradon et al (6,272,933) and further in view of Ott et al (6,068,609).

Gradon discloses a system for delivering a supply of gases to a patient (figure 5). Gradon discloses a gases supply (1) providing a flow of gases (indicated by arrows), a humidifier (10) receiving gases from the gases supply which is capable of humidifying the gases up to a level of humidity prior to delivery to a patient (13).

Gradon discloses a conduit (14) conveying the flow of gases from the humidifier to the patient (13), a sensor (19) to sense the humidity, temperature or flow rate of the flow of gases, wherein the sensor in use is releasably coupled in line between the humidifier (10) and the conduit (14). See: figure 3. However, Gradon lacks the sensor being exposed to a flow of gasses through a filter material.

Ott teaches an in line humidity (138) and temperature sensor (136) apparatus that exposes sensors (136 & 138) to gases after they have flowed through a filter material (130, 131, 132) and a heater.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have added a filter material and heater upstream from the humidity and temperature sensors as taught by Ott, to the humidification system disclosed by Gradon in order to obtain a humidified gas delivery system that could provide additional heating and humidification to gasses delivered to a patient.

Regarding claim 3, Gradon discloses an open tubular section (42) coupled to a sensor (via 31) and the sensor is exposed to the flow of gases through the open tubular section. See: figure 3.

Regarding claim 4, Gradon discloses sensors contained in a housing (31) that extends through an open tubular section (42) and at least part of the housing is exposed to said gases flow.

Regarding claim 6 Gradon discloses an open tubular section with a port (41) that said housing (31) is sealably connected to. See: figure 3.

Regarding claim 8, the combined references teach a housing (31 of Gradon) exposed to said flow of gases flow and Ott teaches the housing being covered by a filter material (130. 131 & 132).

Regarding claim 10, Ott teaches a port (190) that is covered by a filter material (130).

Regarding claims 11-12, Ott teaches filter material that is semi-permeable or hydrophilic material. See: col. 4, line 64 - col. 5, line 13.

Regarding claims 13-14, Ott teaches a filter material that is a microporous media. See: col. 4, line 64 - col. 5, line 19.

Regarding claim 15, Ott teaches a system that has a sensor heater (134) which would provide heat to the sensor of Gradon (34).

Regarding claim 16, Ott teaches a housing (122) comprising a heater (134), a humidity sensor (138) and a temperature sensor (136) contained within the housing.

Regarding claim 17, Gradon discloses a humidifier (10) with a humidification

chamber (4) adapted to receive a volume of water (8) and a water heater (9) that heats the water. The flow of gases passes through the humidification chamber, via a gases inlet (3) and out via a gas outlet (12) and the flow of gases is humidified by evaporating water. See: col. 7, lines 64-66.

Regarding claim 26, Gradon discloses a humidifier (10) with a controller (11) to control the water heater (9) and the level of humidity or temperature of the flow of gases flow. See: col. 7, lines 50-63.

Regarding claim 27, Gradon discloses sensors (34 & 35) that are connected to a controller (11) and conveys a sensed level of humidification of the flow of gases to said controller, and the controller controls the water heater (9) to alter said sensed level of humidification of said flow of gases to a predetermined humidification level. See: col. 13, line 58 - col. 14, line 20.

Regarding claim 28, Gradon discloses a gas outlet temperature of 37°C and containing 44 mg of water vapor per liter, thus meeting the predetermined humidification level as claimed. See: col. 14, lines 4-13.

Regarding claim 29, Gradon discloses connections formed on the open tubular section (42) wherein one side is connected to the humidifier and the other side is connected to a conduit that leads to a patient. See: col. 10, lines 28-47 and figures 3 & 4 wherein the tubular connector is connected to 43 & 44.

Regarding claim 30, Ott teaches connections (124, 126) that are friction fittings or bayonet fitting. See: figure 2.

Regarding claim 31, Gradon discloses a sensing device (34 & 35) to sense humidity and temperature of a flow of gases after said flow of gases have been humidified by a humidifier (10) and providing feedback to a controller (11) which controls said humidifier a sensing device with an open tubular section (42), a sensor (34 & 35), wherein the open tubular section is coupled to the sensor, such that the sensor is exposed to the flow of gases and Ott teaches an open tubular section (122) with sensors (136 & 138) that are exposed to a flow of gases through filter material (130, 131, and 132).

Regarding claim 32, Gradon discloses a housing (31) containing a sensor (34 or 35), and the housing extending through or residing within the open tubular section (42) and at least part of said housing being exposed to the flow of gases.

Regarding claim 33, Ott teaches the filter material is a semi-permeable or hydrophilic material. See: col. 4, line 64 - col. 5, line 13.

Regarding claim 34, Ott teaches a filter material that is a microporous media. See: col. 4, line 64 - col. 5, line 13.

Regarding claims 35-36, Ott teaches a sensing device wherein the sensor has a heating element attached to the housing (via 174), which would provide additional heat to the gases; thus it would be reasonably expected that it would minimize saturation of the sensor when the heating element is on as compared to when the heating element is off.

Response to Amendment

9. Applicant's amendment to the specification is objected to because replacement paragraphs must include markings to show the changes. See: MPEP 714 (II)(B) - Amendments to the Specification.

Response to Arguments

10. Applicants' argument that a new Declaration and Power of Attorney is not required because the non-initialed and/or non-dated alterations were present at the time of execution is not convincing. See: MPEP, Appendix R -Patent Rules, 1.52 (c)(1). In the instant case, the alterations were not dated, initialed or signed on the same sheet.

11. Regarding applicants' argument that Murray does not discloses a system or sensor device wherein the sensor is exposed to the flow of gases through a filter material because the microporous sheet material 18 in Murray acts as a barrier between a water source and the flow of gases has not been found convincing.

The microporous material 18 of Murray would inherently allow for the passage of gas (i.e. it is micoroporous). Murray even describes the microporous wall as being permeable to vapor but substantially impermeable to liquid. See: col. 2, lines 34-45. Thus, it is clear gas would inherently flow through the microporous wall (filter) thus meeting the filter limitation as claimed. Finally, applicants have described and claimed a microporous media as a filter material (claims 13, 14, & 34); therefore, it is clear that the microporous wall disclosed by Murray meets the filter material as claimed.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

13. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771